REMARKS

I. Status of the Claims

By this Amendment, claims 1-10 have been amended, and claims 1-18 are pending and examined. Claims 1-9 have been amended to replace "solvate" with "hydrate," and claim 10 has been amended to further recite "at least one pharmaceutically acceptable carrier." These amendments are supported by the Specification and claims as originally filed, as discussed further below. Therefore, no new matter has been added.

II. Rejections Under 35 U.S.C. § 112

A. Claims 1-9

Claims 1-9 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description and enabling support with respect to the term "solvate." (Office Action, pgs. 2-3 and 5.) The Office indicates that there is "no actual reduction to practice of any compound to form solvate/hydrate with any solvent or water," and further, that "[n]o examples, no process of making, no starting material or operability can be found for any compound encompassed by the Markush formula to have the ability in forming what solvate." (Office Action, pgs. 3 and 5.)

Without conceding the rejection and in an effort to advance prosecution, the present amendments replace "solvate" with "hydrate." To the extent that the Office maintains the rejection of claims 1-9 as lacking written description and enabling support with respect to the term "hydrate," Applicants respectfully disagree and traverse the rejection for the following reasons.

The test of enablement is whether one of ordinary skill in the art could make or use the invention, based on the disclosure in the specification coupled with information known in the art without undue experimentation. *United States v. Telectronics, Inc.*, 8 U.S.P.Q.2d 1217, 1223 (Fed. Cir. 1988). Applicants respectfully submit that the claimed invention is disclosed and described in a manner sufficient to enable one skilled in the art to practice it. For example, the specification discloses that:

> The compound (I) may be a solvate of water [i.e., hydrate] or acetonitrile. The number of hydration of the hydrated compound of the present invention may be fluctuated generally in accordance with a synthetic method, a refining method, or crystallization conditions and it may be in a range of 1 to 5 water molecules per 1 molecule of the compound.

(Specification as-filed, pg. 10.) In addition, the preparation of hydrated compounds of formula (I) is repeatedly exemplified in the as-filed Specification:

- elemental analysis indicating that **compound (4) is a 1/10 hydrate** (pg. 13),
- elemental analysis indicating that **compounds (9) and (10) are 1/4 hydrate** (pg. 15),
- elemental analysis indicating that **compound (17) is a 1/5 hydrate** (pg. 17) ,
- elemental analysis indicating that **compound (19) is a 4/3 hydrate** (pg. 18),
- elemental analysis indicating that **compound (20) is a 1/10 hydrate** (pg. 19),
- elemental analysis indicating that **compound (25) is a mono hydrate** (pg. 20).

Applicants respectfully submit that based on this disclosure, a skilled artisan would know how to make and use hydrates of the compounds of formula I without undue experimentation. Moreover, the Office has provided no evidence or reasoning to the contrary.

Further, as discussed above, hydrated compounds of formula I are exemplified in the as-filed Specification, including pages 13, 15, and 17-20. Thus, there is also written description support for the claimed subject matter.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the § 112 rejections of claims 1-9.

B. Claims 10-18

Claims 10-18 were rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking written description and enabling support with respect to compositions for and the treating of stroke, head injury, Parkinson's disease and tinnitus. (Office Action, pg. 4-6.) The Office indicates that there is "no description or reducing to practice of the compounds being able to have efficacy on the NR2A receptor," and that there is no evidence to link the analgesic properties of the claimed compounds with efficacy in treating non-pain related disorders such as stroke, head injury, Alzheimer's disease, Parkinson's disease, or tinnitus. (Office Action, pgs. 4 and 6.) Applicants respectfully disagree and traverse the rejections for the following reasons.

The written description requirement is met where the Specification reasonably conveys to one of ordinary skill in the art that, as of the filing date, the inventor had possession of the claimed subject matter later. *See In re Edwards*, 568 F.2d 1349 1351-52 (C.C.P.A. 1978). There is a strong presumption that the Specification and claims as originally filed meet the written description requirement. (M.P.E.P. 2163 (I)(A).) Consequently, the Office has the initial burden of "presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims." (M.P.E.P. § 2163 (citations omitted).)

In the present case, the burden has not been met. To the contrary, claims 10-18, directed to pharmaceutical compositions or methods for manufacturing are fully supported and enabled by the Specification.

First, the specification clearly discloses possession and enablement of the claimed compositions, including different types of formulations (granule, tablet, capsule, injectable), additives (disintegrator, binder, lubricant, etc.,), and dosing. (*See, e.g.*, pg. 11, ln. 15-22.) Therefore, there should be no question about written description support and enablement of the claimed compositions or methods of manufacture. Indeed, Applicants respectfully submit that the Office has presented no evidence or basis for a contrary finding.

Second, the specification contains specific evidence demonstrating the binding efficacy of claimed compounds for the NR1/NR2B receptor, thus demonstrating antagonistic activity. (*See e.g.,* Specification as-filed at Examples 1-4.) Indeed, the specification provides experimental tests performed on Wistar rat brains demonstrating the binding efficacy of the claimed compounds specific for the NR1/NR2B receptor and analgesic activity. (*See e.g.*, Experiment Examples 1-4.) Antagonistic activity to the NR1/NR2B receptor is disclosed to be effective for treating Parkinson's disease, stroke, migraine, tinnitus, and head injury. (*See, e.g.*, pg. 2, ll. 34- pg. 3, ll. 3; pg. 3, ll. 34- pg. 12, ll. 8.) This disclosure is further supported by citation to numerous references. (*Id.*) More specifically, the specification includes the following disclosures:

- Experimental Tests 1 and 2 shown strong binding affinity to the NR1/NR2B receptor.

- Antagonistic activity to the NR1/NR2B receptor is disclosed to be effective for treating Parkinson's disease, stroke, migraine, tinnitus, and had injury. (*See e.g.,* Specification as-filed at pg. 2, line 34 - pg. 3, line 3; *see also* pg. 3, line 34 - pg. 12, line 8)
- Specific analgesic effects are shown in Experimental Tests 3 and 4.
- The absence of psychosis side effects is also shown Experimental Tests 3 and 4
- In vivo analgesic activity in sown in Experimental Test 4
- Compounds having NR1/NR2 receptor affinity are disclosed as useful for pharmaceutical compositions, as provided at, *inter alia*, pages 1-10 of the specification

Although the Office's position rests on the alleged absence of a reduction to practice showing NR2A receptor activity, it is noteworthy that the written description requirement may be satisfied even without working or prophetic examples are not required to satisfy the written description requirement. For example, adequate textual information is sufficient if it shows that the inventor possessed the claimed invention. In *Falko-Gunter v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006), the court upheld the grant of priority to the senior party, finding that the inventor's earlier-filed applications provided an adequate written description of the poxvirus vaccine count even though those applications disclosed only herpesvirus examples because the specification provided three textual passages that stated that poxvirus could be used. The *Falko-Gunter* court concluded that such passages were sufficient to show adequate written description even though the specification did not show a reduction to practice of the count.

The present situation is similar to *Falko-Gunter*, and Applicants need not show reduction to practice for each NR2 receptor. To the contrary, as was the case in *Falko-Gunter,* the written description standard would be met even without further express examples of NR2 receptor activity.

Applicants respectfully submit that the Office fails to offer sufficient reasons or evidence why one of ordinary skill in the art would not have recognized that Applicants were in possession of the presently claimed compositions, especially in view of the specific disclosure discussed above.

With respect to enablement, there is a strong presumption that a specification, having a disclosure "which contains a teaching of the manner and process of making and using an invention" complies with the enablement requirement "unless there is a reason to doubt the objective truth of the statements" in the specification. (*See* M.P.E.P. § 2164.04 (citing *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)).) Here, the as-filed specification teaches methods for making and using the subject matter of claims 10-18. Applicants respectfully submit that one of ordinary skill in the art would have been able to practice the claimed invention without undue experimentation, and that the Office has presented no evidence to the contrary. Thus, the enablement requirement is met.

In particular, the Specification discloses exemplary methods for making compounds of formula (I). (*See* Specification as-filed at pgs. 4, 11-22.) In addition, the Specification discloses exemplary doses and administration routes for practicing the claimed invention. (*See* Specification as-filed at pg. 11.) Even without more, this disclosure is more than sufficient to meet the enablement requirement.

In addition, however, the Specification also provides working examples of practicing the claimed invention. The examples on pages 22-27 demonstrate binding affinity, specific antagonistic effect, and effect as an analgesic. For these additional reasons, Applicants respectfully submit that the Specification complies with the enablement requirement. Accordingly, withdrawal of these rejections is respectfully requested.

III. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

If there is any fee due in connection with the filing of this Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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